

### **REMARKS**

Solely and in order to facilitate prosecution, and without acquiescing to the propriety of the Office Action's rejections and assertions, Applicants cancel, without prejudice or disclaimer to further prosecution at a latter date in continuation application(s), claims 2-3, 6-7, and 9-13. Applicants additionally add claim 14, which is narrower than previously pending claim 1, which the Office Action has found to be supported by the original parent applications (Office Action, p.3, lines 17-19). Support for the recitation of botulinum neurotoxin being a "complex having a molecular weight of about 900 kD, 700, kD, 500 kD or 300 kD" can be found at least at paragraphs [0039] and [0226] of the instant published application, and at col. 5, lines 8-30 and col. 16, lines 45-17 of parent U.S. Patent No. 6,306,423, filed June 2, 2002, for example.

#### **1. Effective Filing Date**

The Office Action takes the position that claims 1, 4, 5 and 8 as previously amended, find support in the applicant's parent applications. As herein amended, the claim listing includes these claims and a new claim 14. The limitation of a botulinum neurotoxin complex of about "900 kD, 700, kD, 500 kD or 300 kD" is recited in all pending claims. These complexes are the typical sizes of botulinum neurotoxin complexes, as made by the various *Clostridium botulinum* serotypes, as well known in the art.

#### **2. Claim Rejections – Double patenting**

The Office Action has rejected claims 1, 4, 5 and 8 on the grounds of non-statutory obviousness-type double patenting over pending claims in U.S. App. Ser. No. 10/445,142 and U.S. Patents 6,306,423 and 6,585,993. In accordance with MPEP 804.02, the filing these terminal disclaimers to obviate the rejections based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Accordingly, Terminal Disclaimers over U.S. App. Ser. No. 10/445,142 and U.S. Patents 6,306,423 and 6,585,993 are hereby submitted, thus rendering these rejections moot. Accordingly, reconsideration and withdrawal of the rejections are requested.

### 3. Claim Rejections – 35 U.S.C 102 and 103

The Office Action has rejected claims 9-11 and 10 under 35 U.S.C. 102(e) under Abreu '313. Since these claims have been canceled, these rejections are moot and should be withdrawn. Accordingly, the 35 U.S.C. 103(a) rejection of claim 10 in light of Abreu '313 is likewise moot, as is the 35 U.S.C. 103(a) rejection of claims 2, 3, 6, 7, 12 and 13 in light of Abreu '313.

Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 102(e), the Office Action asserting that these claims are anticipated by Singh et al. (USP 6994859). Applicants respectfully traverse the rejection and assert that the disclosure of Singh et al. is misconstrued. The pending claims are limited to complexes that various *Clostridium botulinum* organisms produce, i.e. to complexes that do not result from chemical isolation of various complex components that are subsequently recombined with neurotoxin. Singh et al. does not anticipate the current claims, since Singh et al. is directed to the use of a 33 kDa hemagglutinin polypeptide purified and isolated *from* the type A *Clostridium botulinum* neurotoxin complex (Abstract, cols. 13-15). That is, Singh et al. discloses the isolation and purification of the Hn-33 polypeptide from the type A *Clostridium botulinum* neurotoxin complex (col. 3, lines 64-66), and then combines this polypeptide with isolated botulinum neurotoxin (about 120 kDa, col. 14 lines 40-45 and col. 19). The instant claims are instead limited to implants incorporating botulinum neurotoxin complexes having a molecular weight of about 900 kD, 700, kD, 500 kD or 300 kD. Indeed, the Singh et al. disclosure teaches away from using these molecular weight complexes as presently claimed, and accordingly cannot anticipate the claimed invention. Thus, this rejection should be withdrawn.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a reply in connection with the present application, the required fee of \$1050 is attached hereto, and request continued examination (RCE).

Should there be any outstanding matters that need to be resolved in the present application; the Examiner is respectfully requested to contact Claude L. Nassif at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers (including RCE, extension of time and Terminal Disclaimer Fees) and to refund any overpayment to deposit account 01-0885.

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Respectfully submitted,

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